

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: JANE MASSEY LICATA
LAW OFFICE OF JANE MASSEY LACATA
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Docket System ✓
Status Report ✓
Docket Book ✓

9/14/01 WO

Date of Mailing
(day/month/year)

14 AUG 2001

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference DC-0184		REPLY DUE	within ONE months from the above date of mailing
International application No. PCT/US00/18775	International filing date (day/month/year) 11 JULY 2000	Priority date (day/month/year) 12 JULY 1999	
International Patent Classification (IPC) or both national classification and IPC Please See Supplemental Sheet.			
Applicant THE TRUSTEES OF DARTMOUTH COLLEGE			

1. This written opinion is the first _____ (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I Basis of the opinion
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Rule 66.9(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.9(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.9. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 19 NOVEMBER 2001

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3290	Authorized officer Gabriele E. Bigdsky PH.D. Telephone No. (703) 308-0196
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I. Basis of the opinion

1. With regard to the elements of the international application:^{*}

the international application as originally filed

the description:
pages 1-24, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

the claims:
pages 25-28, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

the drawings:
pages 1-3, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

the sequence listing part of the description:
pages 1-4, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

contained in the international application in printed form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

the description, pages none

the claims, Nos. none

the drawings, sheets/fig none

5. This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	<u>1-5, 10, 17-22</u>	YES
	Claims	<u>6-9, 11-16</u>	NO
Inventive Step (IS)	Claims	<u>1-5, 10, 17-22</u>	YES
	Claims	<u>6-9, 11-16</u>	NO
Industrial Applicability (IA)	Claims	<u>1-22</u>	YES
	Claims	<u>none</u>	NO

2. citations and explanations

Claims 6-9 and 11-16 lack novelty under PCT Article 33(2) as being anticipated by the admission in the description on page 9, lines 24-27 that the combination of EDAC [1-ethyl-3-(3-dimethyl-aminopropyl)carbodiimide hydrochloride] and glycaminide is known as a combination of compounds that inhibits non-pepsin like acid protease.

Claims 1-5, 10 and 17-22 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the type 4 propeptidases nor methods of their use to design or screen inhibitors.

NEW CITATIONS

NONE

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The description is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 5 because it fails to contain an adequate written description of any inhibitor of type + pepstatin peptidases other than EDAC and glycinate. The description is inadequate because: the structure of a chemical compound is not defined by a method of identification of the compound, nor can an undefined compound be used in a method of controlling bacteria.

Claims 6-8 and 9-16 objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not adequately described in writing, as required under PCT Rule 5.1(a)(iii), for the reasons set forth in the immediately preceding paragraph.

Claims 1, 4, 6-7, 9, 15, and 17 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s): TFPP, EDAC and TCPJ are all abbreviations and are all without recitation of the full term after the first occurrence of the abbreviation.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): C12N 9/48; C12Q 1/37; C07K 1/00; A61K 38/00 and US Cl.: 435/212, 23, 24; 530/350; 514/1, 12